WISCONSIN DEPARTMENT OF CORRECTIONS EXECUTIVE DIRECTIVES 3099 E. Washington Ave. P.O. Box 7925 Madison, WI 53707-7925 (608) 240-5000		
	Original Effective Date: n/a	New Effective Date: 10/7/2019
	Reference: Revised	Date of Approval: 10/7/2019
	By: Kevin A. Carr	
	Owner: Office of the Secretary Research Unit	

EXECUTIVE DIRECTIVE # 36

Subject: Human Subject Research Request Process and Procedure

I. Authority

The Secretary of the Department of Corrections (DOC), as the head of a principal administrative agency within the executive branch of Wisconsin state government, has the power and duty to issue an executive directive to plan, direct, coordinate and execute the functions vested in the agency in carrying out programs and policies within the limits established by the legislature under
s. 15.001 (1),
s 15.01 (5),
s. 15.01 (8),
s. 15.04 (1) (a) and
s. 15.14, Wis. Stats.

References:
Wis. Admin. Code § DHS 92.08, Criminal Commitments
Wis. Stats. §51.30(4)(b)3, Records, State Alcohol, Drug Abuse, Developmental Disabilities and Mental Health Act
Wis. Stats. §51.61(1)(j) and (4), Patients' Rights
Wis. Stats. §§146.82(2)(a)6, Health Care Records, Miscellaneous Health Provisions
Wis. Stats. §252.15(2m)(b)1 HIV test results, Communicable Diseases
Wis. Stats. §938.78(2)(L)Confidentiality of Records, Juvenile Justice Code
34 C.F.R. §99.31 (b)(2) Family Education Rights and Privacy Act (FERPA),
42 U.S.C.A. § 290dd-2(b)(2)b, Confidentiality of Records
42 C.F.R Part 2, Confidentiality of Substance Use Disorder Patient Records
45 C.F.R. Part 164.512(i), Health Insurance Portability and Accountability Act (HIPAA)
The Belmont Report, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
Executive Directive 75, Protection of Confidential Information
Standards for Health Services in Prisons, National Commission on Correctional Health Care

II. Background

The DOC supports and encourages research both in the field of criminal justice and in other areas related to the Department, as it seeks to advance the understanding, treatment, and rehabilitation of those individuals under its custody and care. To this end, the DOC shall assure that research carried out under its authority is held to a high standard and that persons who are subjects of research are protected. The purpose of this Directive is:

- To describe how to apply for research at the DOC, the types of research allowed, the responsibilities of the DOC, the responsibilities of the researcher(s), and the requirements for privacy and security;
- To bridge the gap between research and criminal justice practice by encouraging research projects that will increase the understanding of offender populations, rehabilitative programming, correctional practices, and criminal justice issues more generally.

III. Definitions, Acronyms & References

"Data" means information that the DOC's stores, manages, or maintains. Data may pertain to "confidential information."

"Confidential Information" means communication, records, materials, and knowledge prohibited from disclosure or misuses by law, rule, order, regulation, DOC policy, or otherwise established by the Department. Examples of data concerning confidential information include but not limited to: health care records (medical, dental, mental health, and alcohol and drug abuse), educational records, juvenile records, pre-sentence investigations, and psychological reports. .

"DAI" means the Division of Adult Institutions.

"Data Request" means a formal request to the DOC for Data.

"DCC" means the Division of Community Corrections.

"DJC" means the Division of Juvenile Corrections.

"DOC" or "Department" means the Wisconsin Department of Corrections.

"DOC-Operated Facility" means any building operated by the DOC (e.g. institutions, probation and parole offices, juvenile facilities, etc.).

"Employee" means any person employed by the Department of Corrections, including limited term employees, project employees, permanent or probationary employees, interns, students, volunteers, and contracted workers.

"External Research Projects" means research that is not conducted by DOC employees during the performance of their assigned duties. External research projects do not include Informational Requests or Survey Requests.

"Informational Request" means a request for information concerning inmates, offenders, youth, employees, operations, policies, or programs of the Department. An informational request is a request for a specific piece of information.

"Informed Consent" means a signed statement by a research participant indicating that he or she fully understands the research protocol, expectations for participation, risks and benefits associated with participation, and the option to freely discontinue participation at any time.

"Inmate" means an offender who is currently confined in a prison as defined under, Wis. Stat. s. 302.01. .

"Institutional Review Board (IRB)" means a committee (often associated with a university or college) that has been formally designated to approve and monitor research involving human subjects; the committee is intended to protect the rights and welfare of research subjects.

"Internal Research Projects" means Department-sponsored research that includes data collection with human subjects.

"Liaison" means an employee who coordinates communication between the researcher and the DOC-Operated Facility.

"Minimal Risk" means the probability and degree of harm or discomfort anticipated during the course of the research is no greater than the harm or discomfort encountered in the course of one's daily routine or during the performance of routine physical or psychological examinations.

"Offender" means any individual who is or has been involuntarily confined or detained in a DOC adult institution or center, under probation or parole, extended supervision, or under intensive sanctions supervision. The term encompasses individuals (a) sentenced to such an institution under a criminal or civil statute; (b) detained in other facilities by virtue of statute or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution; (c) detained pending arraignment, trial, or sentencing; or (d) under field supervision.

"OOS" means Office of the Secretary.

"Participant" means an offender, inmate, or youth under the care and custody of the department or an employee being studied in a research project.

"Privacy Board" is a review body established to act upon requests for a waiver or an alteration of the HIPAA Authorization requirement under the HIPAA Privacy Rule for uses and disclosures of protected health information (PHI) for a particular research study.

"Research" is a procedure for systematic inquiry with the purpose of increasing knowledge or facilitating problem solving.

"Research Activities" means a project, paper, or study designed primarily to produce new data, information, or understanding of corrections, criminal justice, management, or other issues of relevance to the Department. Secondary data sources (existing Department datasets) may supplement such research.

"Research and Policy Unit" is a unit within the Department of Corrections responsible for leading research and evaluation efforts for the department and is under the authority of the OOS.

"Research Review Committee (RRC)" means a DOC committee comprised of a group of individuals appointed by appropriate division leadership who are responsible for reviewing all research proposals submitted to the Department. After review of the Research Requests, the members of the RRC provide advisory opinions to the Director of Research and Policy, who has the approving authority. Research Requests will be reviewed to determine whether they are in compliance with guidelines dealing with the use of human subjects in research and with professional research standards. The committee and any presiding member shall have advisory powers only. The committee does not have any collective responsibilities, authority, power, and duties vested in the body as a whole, distinct from the individual members.

"Research Request" is a request for "Research" that uses DOC data; treats DOC employees, inmates, offenders and/or youth as participants; and/or will be conducted at a DOC-operated facility. Research Requests are subject to review by the Research Review Committee, and as such, are considered distinct from Data Requests, Informational Requests and Survey Requests.

"Researcher" means the primary person responsible for submitting the research proposal and overseeing completion of the project.

"Subject" has the same meaning as Participant.

"Survey Request" means a request for public information on the correctional population, employees of the Department, or Department policies and practices, which treats the Department itself as the participant, often along with other non-DOC correctional organizations.

"Working Days" means all days except Saturdays, Sundays, and legal holidays.

"Youth" means any individual who is under the care and custody of the Division of Juvenile Corrections, either housed in a juvenile correctional facility or under supervision in the community.

IV. Scope

This policy applies to persons who wish to conduct research or evaluate data regarding human subjects. Human subjects include offenders, youth, and employees. The scope of this

policy includes external and internal research projects. Informational requests or survey requests are outside of the scope of this policy.

V. Policy

The purpose of this policy is to establish guidelines that govern voluntary participation by employees and/or those under the care and custody of the Department.

The Department shall encourage cooperation between employees and researchers in assisting with research design, data collection, and publication. Research activities using generally accepted research methods and standards may contribute to correctional knowledge, to more efficient and effective facility operations, conservation of resources, benefits to current or future inmates, and increased public safety.

Researchers are responsible for ensuring that the protocols of their proposed research comply with applicable federal and state laws, case law and DOC policies and procedures. Researchers shall comply with all laws in effect at the time of the submission of a proposal. The law that provides the most stringent protection of privacy rights shall be the controlling law with respect to each type of information. Researchers should consult with legal counsel as needed. Medical research on human subjects, including research on substance use disorders, will be reviewed with additional scrutiny, as outlined in Section VI, Sub-Section F of this policy.

Researchers are responsible for costs incurred by special computing software, special equipment, employee resources, or any other required resources. If the Department covers any of the above costs, the researchers may be required to reimburse the Department for expenses incurred. Such expenses can be waived by the Director of Research and Policy.

In order to ensure the rights and interests of subjects, all research efforts will follow the procedures outlined in this document, DOC policies, professional and scientific ethics, and comply with state and federal guidelines. Research activity cannot begin until written approval is acquired from the Director of Research and Policy.

Researchers may not compensate subjects for their participation unless specifically authorized by the Director of Research and Policy.

VI. Procedure

A. Procedure for Requests

1. Researchers must complete the Research Request Application and submit the form electronically to DOCResearchRequest@wisconsin.gov

2. Researchers are also required to submit an Application Supplement Conviction Record (background check), DOC form 1098D to DOCemployeebackgroundchecks@wi.gov or mailed to: Wisconsin Department of Corrections, Research and Policy Unit, 3099 East Washington Ave., P.O. Box 7925, Madison, WI 53707-7925. The submission should include the following:
   a. The primary researchers' name.
   b. Research request title and brief project synopsis.
   c. DOC facilities the researcher is requesting to enter.

3. Employees conducting research for reasons outside of normal work duties must complete the Research Request Application above along with the DOC-138A. Employees shall submit a DOC-138A form which indicates that such research shall not be conducted during regular work hours, unless specifically authorized by the Director of Research and Policy and relevant supervising authorities of the employee. Employees are not permitted to conduct internal research projects without authorization.

4. Individuals submitting a research request for academic purposes (for example, a class or term paper, an internship paper, a dissertation, or a thesis), must be accompanied by their University's IRB approval. If IRB approval cannot be granted until after the Director of Research and Policy has approved the research, the members of the RRC will recommend that the Director of Research and Policy grant conditional approval, stating that the research must not begin until official IRB approval has been received by the Department.

5. All research proposals submitted by students (undergraduate or graduate level) must have a research advisor's signature on the DOC-1198 indicating both of the following: (a) the student's proposal has been reviewed and (b) the quality of the submission meets the college or university standards for quality and soundness of design. The student's academic advisor's contact information must be included in Part IV: Description of Project Employees.

6. The Department will not approve any research requests submitted by inmates, offenders, or youth under the custody or supervision of the Department requesting permission to conduct research, as defined in this Executive Directive.

7. The request must be submitted electronically to the Research Review Committee at DOCResearchRequest@wisconsin.gov.

8. A written response to acknowledge receipt of the research request materials will be made to the requestor within three working days of the receipt of the request. The notification shall provide an anticipated date that the members of the RRC will review the request.

B. Procedure for Review

1. The members of the RRC shall review all research proposals and make a recommendation to the Director of Research and Policy as to whether they should proceed for further review. Research proposals will only be reviewed if they offer a clear and complete explanation of the objectives of the research; its estimated impact; relation to previous research; and description of the methods, plan for analysis, and expected outcomes of the research. If all members of the RRC recommend that a proposal does not proceed, the proposal will be referred to the Director of Research and Policy for a final decision. The members of the RRC will automatically recommend that a proposal be denied under the following conditions:
   a. The research had already begun prior to DOC approval.

b. The research requires excessive resources from the Department.

2. Research requests will be prioritized based on their alignment with the DOC's mission and strategical goals; their relevance to current legislation and legal mandates; and the availability of resources to support the requests. Research requests may be denied by the Director of Research and Policy if they are not prioritized by the RRC during the review process.

3. Research requests shall be reviewed using the following criteria:
   a. Statutory or legislative authority to conduct the research.
   b. Statutory or regulatory authority to acquire or access the requested information.
   c. Study justification.
   d. Appropriateness of study design to answer research question(s).
   e. Protection of human subjects.
   f. Security and privacy standards for DOC confidential data, including personal information as defined by Executive Directive 75.
   g. Need and availability of Department resources.
   h. Potential adverse impact on the security and safety of the Department, its facilities, and employees.
   i. Voluntary participation by participants.

4. The RRC may function as a privacy board for purposes of HIPAA regulations under 45 CFR s. 164.512(i).

C. Advisory Process

1. Requests received less than one week prior to the next RRC meeting will not be reviewed until the following meeting.

2. The appropriate division representative will share materials pertaining to the request with the affected division for their review and recommendation.

3. Research requests involving disclosure of DOC Confidential information shall be reviewed by the DOC Privacy Officer and/or DOC HIPAA Compliance Officer for issues of privacy and confidentiality. The members of the RRC will review the proposal, delineate the pros and cons of the request, and each provide an advisory opinion. The Director of Research and Policy may consider the RRC members' advisory opinions prior to making their final decision. If the Director of Research and Policy denies the request, they may give the researcher an opportunity to address the reasons for denial and submit a revised proposal.

The Department reserves the right to deny any proposals submitted to the RRC. The Department may impose conditions on the proposed research design or methodology to address concerns such as resources, security, or confidentiality issues. In the event that conditions are imposed, including the execution of a Memorandum Of Understanding (MOU) between the DOC and the research requestor(s), the Department shall notify the researcher of the conditions in the research approval notification.

D. Expedited Review
The Department may review a request on an expedited basis if one of the following applies: (a) the request is for an extension of an existing project; (b) the request has been previously approved by the Department; or (c) the request is deemed by the Director of Research and Policy to not require a full review. An example of a proposal, which may be reviewed under this provision, includes interviewing or surveying offenders already enrolled in a longitudinal research study.

E. Continuing Review

1. Researchers must submit progress updates every six months until the completion of the project or more frequently as requested.

2. Any changes to the research request or protocols must be approved in writing by the Director of Research and policy prior to implementation.

F. Biomedical, behavioral, and other medical research using inmates as subjects must be consistent with established ethical, medical, legal, and regulatory standards for human research. The researcher must demonstrate awareness of and adhere to associated federal and state statutes as it pertains to the extra protections for such research, in regards to protection of human subjects, and to federal compliance as it relates to both HIPAA and substance use disorder patient records.

G. Research activities shall commence within three months of the approval date. If research activities do not commence within three months, the Department may require the researcher to resubmit the request for re-approval with an explanation for the delay.

H. A liaison may be assigned to assist the researcher at the researcher location. The liaison shall serve as a resource regarding DOC policy and procedures and aid in compliance with those policies and procedures to maintain integrity throughout the study period.

I. The Department may suspend or terminate both previously approved research and research that has been carried out without approval at any time. The Department shall notify the researcher in writing of its decision.

J. Upon completion of the project, the researcher is required to submit a copy of the final report to the Department. Research participants may also request additional copies of the final report.

K. If the researcher intends to publish the research, they must submit the paper to the Department at least 30 days prior to submission for publication. The Department will review the paper for accuracy and integrity, and may recommend revisions prior to publication. The Department may deny any request for publication at their discretion. Following publication, the researcher shall send a copy to the Director of Research and Policy.

VII. Informed Consent to Participate in Research and Authorizations to Disclose Confidentiality

A. As human subjects of research, participants have a right to expect that confidential information gathered about them for a particular study will not be divulged in a manner that identifies any individual. The expectation of confidentiality extends not only to the procedures by which the research is carried out and to the published findings of the research, but also to the non-research related communications of the researcher.

B. All proposals to conduct research that involve human subjects or that require information about human subjects must address the issues of privacy and confidentiality in the research protocol. The privacy of research participants shall be respected. The members of the RRC will review the protocol to ensure that the research will not directly or inadvertently result in the disclosure of confidential information.

C. All research materials will be maintained by the researcher for a minimum of five years, after which time materials will be destroyed by deleting, shredding, or burning.

D. The researcher must obtain written informed consent from participants before beginning research, unless granted an exemption from this by the RRC or an IRB.

E. Researchers may not provide compensation or other rewards to participants for their participation in research, unless special permissions is granted by the Director of Research and Policy.

F. When appropriate, employees may be informed of an offender's inclusion in research activities.

G. An informed consent shall include all of the following elements in writing:

1. A brief statement of the research purpose.

2. An explanation of the research procedures.

3. A description of the potential discomforts and risks, as well as an explanation as to how those discomforts and risks will be addressed.

4. A description of the potential benefits to the subject or others.

5. A disclosure of all alternative procedures.

6. Contact information for research personnel responsible for answering questions and concerns.

7. A written statement that the participant may withdraw consent at any time or discontinue participation at any time without penalty. Procedures for withdrawal should be noted, as should the circumstances under which researchers may terminate the subject's participation without the subject's consent.

8. A statement that any information disclosed to the researcher will not be disclosed to the Department, except where the researcher has knowledge, information or

suspicion that the participant has experienced sexual abuse or sexual harassment during confinement, is a threat to their own safety, the health or safety of another person, or to the security or orderly operation of any DOC-operated facility, especially where a participant has expressed an intention to harm self or others.

9. A statement regarding the confidentiality of records/data, how that confidentiality will be maintained and the time period during which consent is effective.

10. A space for the signature of the individual whose records are being disclosed as well as the individual/organization to which the disclosure is made.

11. If the researcher wants to quote participants in any manner, separate authorization is required by an additional space for signatures and date. Confidentiality and privacy must be respected as is appropriate for the participants' interest.

H. Standard procedure for research involving review, collection, or creation of individually identifiable protected health information requires that the participant sign an Authorization for the Use and Disclosure of Protected Health Information (DOC-1163A) authorizing the DOC to disclose the protected health information to the researcher. The HIPAA Compliance Officer or Office of Legal Counsel shall review all research proposals that involve the review, collection, or creation of protected health information.

VIII. Research Review Committee

A. The Research Review Committee consists of no fewer than five people. Each Division Administrator shall appoint a representative to the committee. An employee from the Research and Policy Unit will serve as the committee chairperson. Additional representatives may be appointed as deemed appropriate by the Director of Research and Policy.

B. Members of the RRC should have background and experience in a field of human research and/or an understanding of correctional operations.

C. If a member of the RRC submits a research request, they may not have direct or indirect involvement with the review of the research proposal.

D. The RRC will meet as necessary to provide reasonable responsiveness to research applications and reviews.